

Complete Summary

GUIDELINE TITLE

Cancer Care Ontario and American Society of Clinical Oncology adjuvant chemotherapy and adjuvant radiation therapy for stages I-IIIA resectable non-small-cell lung cancer guideline.

BIBLIOGRAPHIC SOURCE(S)

Pisters KM, Evans WK, Azzoli CG, Kris MG, Smith CA, Desch CE, Somerfield MR, Brouwers MC, Darling G, Ellis PM, Gaspar LE, Pass HI, Spigel DR, Strawn JR, Ung YC, Shepherd FA. Cancer Care Ontario and American Society of Clinical Oncology adjuvant chemotherapy and adjuvant radiation therapy for stages I-IIIA resectable non-small-cell lung cancer guideline. J Clin Oncol 2007 Dec 1;25(34):5506-18. [76 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Stages I-IIIA resectable non-small-cell lung cancer (NSCLC)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
 Management
 Treatment

CLINICAL SPECIALTY

Oncology
Radiation Oncology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To determine the role of adjuvant chemotherapy and radiation therapy in patients with completely resected stage IA-IIIA non-small-cell lung cancer (NSCLC)

Specifically, to address the following questions:

- What is the benefit in terms of overall survival and role of adjuvant chemotherapy in patients with completely resected stage I-IIIA NSCLC?
- What is the benefit in terms of overall survival and role of adjuvant radiation therapy in patients with completely resected stage I-IIIA NSCLC?

TARGET POPULATION

Post-operative non-small cell lung cancer (NSCLC) patients

This guideline does not address postoperative NSCLC patients with positive margins (i.e., microscopic residual disease, R1 resection) or macroscopic residual disease (R2 resection).

INTERVENTIONS AND PRACTICES CONSIDERED

1. Adjuvant cisplatin-based chemotherapy
2. Adjuvant radiation therapy

MAJOR OUTCOMES CONSIDERED

- Overall survival (primary outcome of interest)
- Disease-free survival
- Recurrence rates
- Adverse effects, toxicity, and complications related to treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Review and Analysis

The Cancer Care Ontario (CCO) systematic reviews on adjuvant chemotherapy and adjuvant radiation. The CCO Lung Disease Site Group (DSG) first published a systematic review on the role of adjuvant radiation therapy and chemotherapy in patients with stage II or IIIA resected non-small-cell lung cancer (NSCLC) in 1997. More recently, two separate systematic reviews were undertaken by CCO to update the original systematic review: one on adjuvant chemotherapy for patients with stage I-IIIa completely resected NSCLC, and one on adjuvant radiation in patients with stage II or IIIA completely resected NSCLC. These systematic reviews have been published elsewhere and serve as the primary source of evidence for this practice guideline.

The Cancer Care Ontario-American Society of Clinical Oncology (CCO-ASCO) Panel literature review and analysis. The Cancer Care Ontario-Program in Evidence Based Care (CCO-PEBC) staff updated the literature searches in August 2006, before the joint CCO-ASCO Panel meeting. Articles were included in the CCO-PEBC systematic reviews of chemotherapy (or radiation therapy) for NSCLC if they were in the following categories:

1. Evidence-based practice guidelines addressing the role of postoperative chemotherapy (or radiation therapy) following complete resection of NSCLC and published since 2000 (to identify trials published since the prior systematic review), or
2. Randomized clinical trials (RCTs) or meta-analyses that
 - a. Compared postoperative chemotherapy (or radiation therapy) versus surgery without chemotherapy (or radiation therapy) in patients with completely resected NSCLC
 - b. Reported overall survival or disease-free survival as a main outcome; or
 - c. Were published in peer-reviewed journals or reported in a conference abstract

Articles published in a language other than English were excluded. Articles lacking information on the stage distribution of the study population were also not considered. Studies involving alkylating chemotherapy agents, alone or in combination with nonplatinum agents, or involving immunotherapy were not included.

NUMBER OF SOURCE DOCUMENTS

Adjuvant Chemotherapy

The systematic review identified eight meta-analyses, and 16 randomized clinical trials (RCTs) relevant to this guideline.

Adjuvant Radiation Therapy

Evidence from a meta-analysis of nine RCTs evaluating postoperative radiation therapy and data obtained from three additional RCTs published after this meta-analysis were reviewed.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Cancer Care Ontario Program in Evidence-Based Care (CCO-PEBC) and the American Society of Clinical Oncology (ASCO) convened a Joint Expert Panel in August 2006 to review the evidence and draft recommendations for these therapies.

Panel Composition

CCO and ASCO convened a Joint Expert Panel consisting of experts in clinical medicine, clinical research, health services research, and related disciplines (biostatistics, medical decision-making, patient-physician communication) with a focus on expertise in lung cancer. Patient representatives were also included on the Panel. The clinical experts represented medical oncology, radiation oncology, and surgical oncology. A steering committee under the auspices of the Health Services Committee (HSC) and the CCO Program in Evidence-Based Care (PEBC) Lung Cancer Disease Site Group (DSG) chose Panel participants for the clinical practice guideline development process.

Consensus Development Based on Evidence

The CCO systematic reviews on adjuvant chemotherapy and radiation therapy were circulated to the CCO-ASCO Joint Panel members in August 2006 for review. The Panel also reviewed the new evidence that had emerged since the completion of the CCO systematic reviews, refined the questions to be addressed by the guideline, and developed recommendations at a meeting at the ASCO Headquarters Office (Alexandria, VA) in August 2006. A draft version of the guideline was circulated to the four co-chairs of the Joint Panel in February 2007

for review and approval. Additional work on the guideline was completed via teleconferences with Panel members. A revised version was circulated to all Panel members in April 2007 for final review and approval. The draft guideline was disseminated to practitioners in Ontario, Canada, and in the United States for external review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Both the Cancer Care Ontario Program in Evidence-Based Care (CCO-PEBC) and the American Society of Clinical Oncology (ASCO) conducted an external review of the recommendations in this guideline. The initial systematic review and practice guideline developed by CCO were distributed to practitioners in Ontario, Canada, for review in October 2004. Feedback was obtained through a mailed survey accompanying the guideline, in which practitioners could rate a number of items, including the quality of the review, whether or not they agreed with the recommendations, and whether they would follow the recommendations in their own practice. Written feedback was also encouraged. Feedback from external reviewers was also solicited by ASCO. ASCO distributed the guideline draft to six oncologists and two patient advocates and asked them to complete a similar form to that employed in the CCO practitioner feedback process. The content of the guideline and manuscript were reviewed and approved by the ASCO HSC, the ASCO Board of Directors, and by the CCO Report Approval Panel before dissemination.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Summary of Recommendations for Adjuvant Cisplatin-Based Chemotherapy for Stages I-IIIA Resectable Non-Small-Cell Lung Cancer	
<i>Stage IA</i>	Adjuvant chemotherapy is not recommended.
<i>Stage IB</i>	Adjuvant cisplatin-based chemotherapy is not recommended for routine

	use.
<i>Stage IIA</i>	Adjuvant cisplatin-based chemotherapy is recommended.
<i>Stage IIB</i>	Adjuvant cisplatin-based chemotherapy is recommended.
<i>Stage IIIA</i>	Adjuvant cisplatin-based chemotherapy is recommended.
<i>General</i>	The use of adjuvant chemotherapy regimens that include alkylating agents is not recommended as these agents have been found to be detrimental to survival.
Summary of Recommendations for Adjuvant Radiotherapy for Stages I-III A Resectable Non-Small-Cell Lung Cancer	
<i>IA/B and IIA/B</i>	Adjuvant radiation is not recommended.
<i>IIIA</i>	Adjuvant radiation therapy is not recommended for routine use because of the lack of prospective, randomized clinical trial data evaluating its efficacy. A clinical trial is underway to determine the advisability of its routine use.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

In general, the literature review supporting these recommendations centered on randomized clinical trials and meta-analyses of data from randomized clinical trials.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate use of adjuvant chemotherapy and adjuvant radiation therapy in resectable non-small-cell lung cancer
- Improved patient outcomes

POTENTIAL HARMS

Adverse effects of treatment

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

It is important to emphasize that practice guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations, and cannot be considered inclusive of all proper methods of care or exclusive of other treatments reasonably directed at obtaining the same result. Accordingly, the American Society of Clinical Oncology (ASCO) and Cancer Care Ontario (CCO) consider adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's individual circumstances. In addition, these guidelines describe administration of therapies in clinical practice; they cannot be assumed to apply to interventions performed in the context of clinical trials, given that clinical studies are designed to test innovative therapies in a disease for which better therapy is needed. In that guideline development involves a review and synthesis of the latest literature, a practice guideline also serves to identify important questions for further research and those settings in which investigational therapy should be considered.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources
Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides
Slide Presentation

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Pisters KM, Evans WK, Azzoli CG, Kris MG, Smith CA, Desch CE, Somerfield MR, Brouwers MC, Darling G, Ellis PM, Gaspar LE, Pass HI, Spigel DR, Strawn JR, Ung YC, Shepherd FA. Cancer Care Ontario and American Society of Clinical Oncology adjuvant chemotherapy and adjuvant radiation therapy for stages I-IIIa resectable non-small-cell lung cancer guideline. J Clin Oncol 2007 Dec 1;25(34):5506-18. [76 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Dec

GUIDELINE DEVELOPER(S)

American Society of Clinical Oncology - Medical Specialty Society
Cancer Care Ontario - State/Local Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

American Society of Clinical Oncology

GUIDELINE COMMITTEE

Joint Cancer Care Ontario- American Society of Clinical Oncology (CCO-ASCO)
Expert Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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The Sarah Cannon Cancer Center; John R. Strawn, MD, Patient Advocate; Yee C. Ung, MD, Toronto-Sunnybrook Regional Cancer Centre

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Expert Panel complied with the American Society of Clinical Oncology (ASCO) policy on conflicts of interest, which requires disclosure of any financial or other interest that might be construed as constituting an actual, potential, or apparent conflict. Members of the expert Panel completed ASCO's disclosure form and were asked to reveal ties to companies with products that might be affected by promulgation of the guidelines. Information was requested regarding employment, consultancies, stock ownership, honoraria, research funding, expert testimony, and membership on company advisory committees. The Panel made decisions on a case-by-case basis as to whether an individual's role should be limited as a result of a conflict. No limiting conflicts were identified.

Note: Although all authors completed the disclosure declaration, the following author(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors in the original journal of publication.

Employment or Leadership Position: None **Consultant or Advisory Role:** David R. Spigel, Genentech (C); Frances A. Shepherd, Pierre Fabre (C), GlaxoSmithKline (C)

Stock Ownership: None **Honoraria:** Peter M. Ellis, Bristol-Myers Squibb; Frances A. Shepherd, Pierre Fabre, GlaxoSmithKline **Research Funding:** Christopher G. Azzoli, Genentech Biooncology, Sanofi-aventis, Allos Therapeutics; David R. Spigel, Genentech, Sanofi-aventis **Expert Testimony:** None **Other Remuneration:** None

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Society of Clinical Oncology \(ASCO\) Web site](#).

Print copies: Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 1900 Duke Street, Suite 200, Alexandria, VA 22314; E-mail: guidelines@asco.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Cancer Care Ontario and American Society of Clinical Oncology adjuvant chemotherapy and adjuvant radiation therapy for stages I-IIIa resectable non-small cell lung cancer guideline. Slide set. 2007. 17 p. Electronic copies: Available in [Portable Document Format \(PDF\)](#) and [PowerPoint](#) from the American Society of Clinical Oncology (ASCO) Web site.
- CCO-ASCO adjuvant chemotherapy and adjuvant radiation therapy for resectable non-small cell lung cancer. Guideline summary. 2007. 4 p. Electronic copies: Available from the [ASCO Web site](#).

Guidelines are available for Personal Digital Assistant (PDA) download from the [ASCO Web site](#).

PATIENT RESOURCES

The following are available:

- ASCO patient guide: adjuvant treatment for lung cancer. 2007 Oct. 4 p. Available from the [Cancer.Net Web site](#).
- Decision aid tool. Stage IB non-small cell lung cancer (NSCLC) cisplatin plus vinorelbine chemotherapy after surgery. 2007. 4 p. Available in Portable Document Format (PDF) from the [American Society of Clinical Oncology \(ASCO\) Web site](#).
- Decision aid tool. Stage II non-small cell lung cancer (NSCLC) cisplatin plus vinorelbine chemotherapy after surgery. 2007. 4 p. Available in Portable Document Format (PDF) from the [American Society of Clinical Oncology \(ASCO\) Web site](#).
- Decision aid tool. Stage III non-small cell lung cancer (NSCLC) cisplatin plus vinorelbine chemotherapy after surgery. 2007. 4 p. Available in Portable Document Format (PDF) from the [American Society of Clinical Oncology \(ASCO\) Web site](#).

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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